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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,577	05/31/2006	Louis Briard	0512-1321	5139

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YOUNG & THOMPSON
209 Madison Street
Suite 500
Alexandria, VA 22314

EXAMINER

COTRONEO, STEVEN J

ART UNIT	PAPER NUMBER
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3733

NOTIFICATION DATE	DELIVERY MODE
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11/24/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No. 10/566,577	Applicant(s) BRIARD ET AL.	
	Examiner STEVEN J. COTRONEO	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,8-11,13,16 and 20-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 8-11, 13,16 and 20-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 states “**further comprising** a femoral insert and optionally a tibial insert...” Claim 21 already claims a femoral insert and tibial insert. It is unclear if the inserts of claim 23 are different from claim 21.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 21-28 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims recite part of the human body in combination with the device, e.g. Claim 21 states “a force generation unit that maintains the knee.” It has been held that a claim directed to or including within its scope, a human being will not be considered to be patentable subject matter under 35 U.S.C. 101. The grant of limited, but exclusive property right in a human being is prohibited by the constitution. *In re Wakefield*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970). For

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examination purposes, all claims will be considered as if such limitations involving the combination with a human were not present.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 8-11, 13, 16 and 20-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eckhoff (U.S. 5,669,914) in view of Rehder (U.S. 4,865,606).

Eckhoff discloses a device (see fig 1 below) for dynamic tensioning of a natural or prosthetic knee joint, with or without a tibial cut being carried out, of the type comprising at least one femoral insert (fig 1, 40) which has a condyle support surface for a femoral implant or bone; at least one tibial insert (fig 1, 60) which has a support surface for a tibial plate for a tibial implant or bone; and means (fig 1, 82) for applying, between the femoral and tibial inserts, a distraction force of a predetermined strength, with or without the kneecap being in position, characterized in that it is constructed so as to allow rotation of the joint and comprises means for maintaining the knee in a state of tension during rotation (col. 3, ll. 63-65), and thus carrying out measurements for various angles of rotation. The device is provided for the inner and outer compartment of the knee (fig 1). The device includes means for measuring the spacing of the surfaces and the distraction force (fig 4, 89 and col. 9, ll. 28-35). The means for applying

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the distraction force comprises a force generation unit (fig 1, 82) and a pair of branches (fig 1, 44).

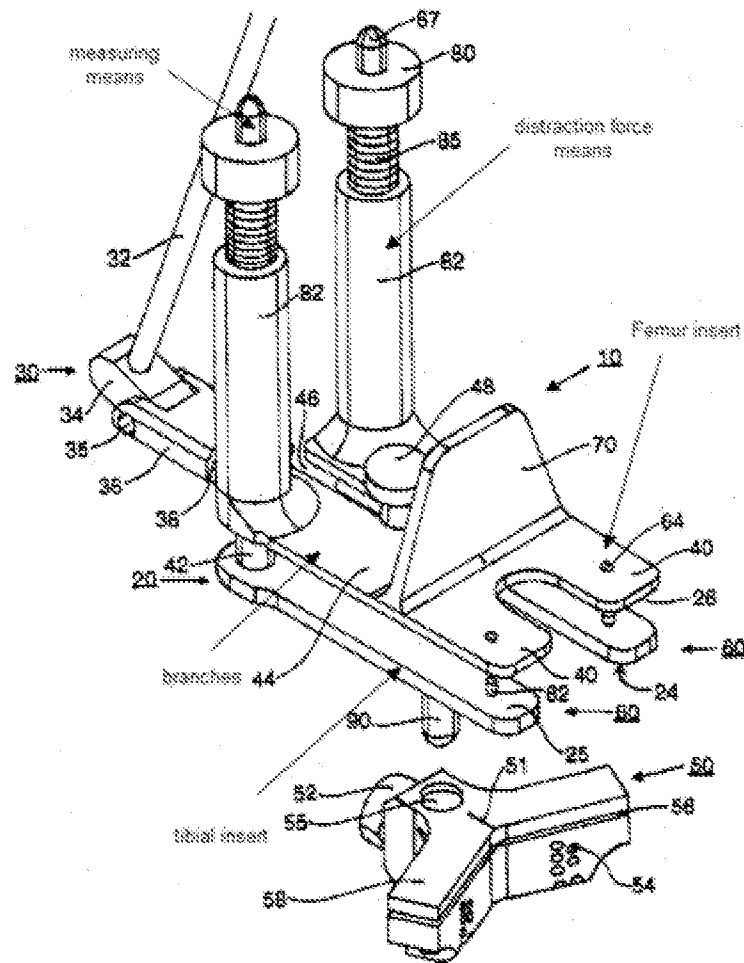


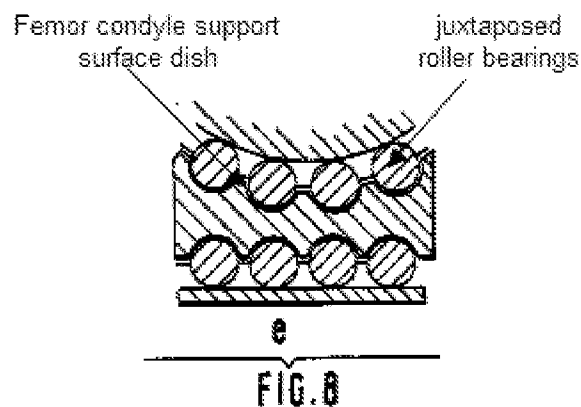
FIG. 1

Eckhoff discloses the claimed invention except for a sliding means for the femoral implant or bone when the knee joint is displaced comprising juxtaposed rollers, and the condyle surface is in the form of a dish.

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Rehder discloses a sliding means for the femoral implant or bone when the knee joint is displaced, comprising juxtaposed rollers (fig 8e top surface) to allow for pure rotational movement of the knee (col. 3, ll. 22-30).

Rehder also discloses the condyle surface is in the form of a dish (fig 8e and col. 7, ll. 7-9) to prevent lifting (col. 7, ll. 7-10).



It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the device of Eckhoff with a sliding means for the femoral implant or bone when the knee joint is displaced comprising juxtaposed rollers, and the condyle surface is in the form of a dish in view of Rehder in order to allow for pure rotational movement of the knee and to prevent lifting.

As to claim 20, Rehder discloses the claimed invention except for the maximum thickness of the inserts is less than or equal to 2.5mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made for the maximum thickness of the inserts is less than or equal to 2.5mm since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Response to Arguments

Applicant's arguments filed 7/24/2009 have been fully considered but they are not persuasive. The applicant argues that the combination of Eckhoff and Rehder is improper. The applicant argues that Eckhoff and Rehder are two different devices performing different functions. The examiner respectively disagrees. In response to applicant's argument that Rehder is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, both Rehder and Eckhoff are concerned with the knee joint and rotation thereof (Eckhoff abstract states "This invention provides a **rotation alignment device** for aligning the tibia with the femur of a patient prior to placement of prosthetic knee components. The device **allows the patient's normal, habitual rotation of the tibia with respect to the femur** to be preserved when the prosthesis is placed." therefore it allows and wants rotation between the knee and tibia contrary to the applicants arguments). Rehder is also designed to allow normal rotation (Rehder abstract states "The invention avoids localized load peaks while accomplishing the **physiological functions of the knee joint during movement and load.**"). Therefore Rehder and Eckhoff are related and modifying Eckhoff with Rehder only aids Eckhoff function and does not hinder it. Applicant argues Eckhoff has antirotation pegs to prevent rotation of the knee. The examiner respectively disagrees. The pegs 62 of Eckhoff are designed to prevent the

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rotation of the two clamp faces (leaves) relative to the other (peg 62 fits into hole 64) and are not designed to prevent rotation of the tibia (col. 9, ll. 14-17 states: "Antirotation peg 62 on each tibial leaf 60 is then engaged with antirotation hole 64 on each femoral leaf 40 to prevent the tibial leaves 60 from rotating with respect to the femoral leaves 40." Nothing in Eckhoff states the rotation pegs are for preventing the rotation of the knee joint.).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **STEVEN J. COTRONEO** whose telephone number is (571)270-7388. The examiner can normally be reached on M-F 730-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. C./

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733